

NOT FOR PUBLICATION

(Docket Entry No. 19)

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

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KAREN MCMILLAN,	:	
	:	
Plaintiff,	:	Civil No. 04-1180 (RBK)
	:	
v.	:	<b>OPINION</b>
	:	
JOHNSON & JOHNSON, et al.,	:	
	:	
Defendants.	:	
	:	

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**KUGLER**, United States District Judge:

In this products liability action, removed on diversity grounds from the Superior Court of New Jersey, Camden County, plaintiff Karen McMillan alleges that her prosthetic knee implant was defectively designed and manufactured. This matter comes before the Court upon motion by defendants Johnson & Johnson, DePuy Orthopedics, Inc., and Depuy, Inc. for summary judgment. For the reasons expressed in this opinion, Defendants' motion for summary judgment will be granted.

**I.**           UNDISPUTED FACTS

DePuy Orthopaedics manufactures a prosthetic implant known as a P.F.C. *Sigma* knee system. On July 12, 2001, McMillan

underwent right total knee arthroplasty surgery, during which she received a P.F.C. *Sigma* Knee System Stabilized Tibial Insert identified as Product Ref. # 96-0432, Lot # 62240A. Defendants sterilized McMillan's P.F.C. *Sigma* tibial insert with gamma irradiation in vacuum foil packaging. (Defs.' Stmt. Undisputed Mat. Facts ¶¶ 1-3; Defs.' Br. 3.)

On August 5, 2001, McMillan suffered from an "infected right knee" involving "coag positive *Staph aureus*" with "obvious purulence" and requiring an "irrigation and debridement." (Defs.' Stmt. ¶ 4.) On December 7, 2001, McMillan told her orthopedic surgeon that her knee kept "catching, cracking and creaking." (Id. ¶ 5.)

On August 15, 2002, McMillan underwent revision surgery on her prosthesis. When McMillan's P.F.C. *Sigma* tibial insert was explanted, the surgeon noted that "the tibia was removed and it was noted to be fairly loose as was the cement around it." The surgeon's medical records reflect that component loosening, rather than polyethylene wear or degradation, made revision surgery necessary. (Id. ¶¶ 6-8.)

On April 13, 2003, McMillan underwent a second revision surgery to address "an eccentrically placed tibial component." The surgeon's medical records reflect that the alignment of the component, rather than polyethylene wear or degradation, made revision surgery necessary. (Id. ¶¶ 9-10.)

McMillan's complaint alleges that her need for replacement of the "lower portion of the knee implant" was "the proximate result of a design defect or manufacturing flaw in Defendants' artificial knee." (Compl. ¶¶ 2, 7.) In her Responses to Interrogatories, McMillan set forth her theory of Defendants' liability as to each count of her complaint: "[The] prosthetic components were sterilized in such a manner as to cause premature degradation and failure of the prosthetic components." (Pl.'s Resps. Interrogs. ¶¶ 19, 21-24.)

McMillan certified:

Between the time . . . my knee was replaced on July 12, 2001 and April 3, 2003, I was not involved in any falls, automobile accidents, sports injuries, or any kind of injury or insult to my right knee. I carefully followed [the orthopedic surgeon's] instructions for the proper care of my prosthesis from the day it was put in on July 12, 2001 until the day of the second revision on April 3, 2003. I used my prosthesis at all times in an extremely careful manner, never banging it or striking it. At no time did I abuse, misuse, or do anything to damage my prosthesis.

(McMillan Cert. ¶¶ 6-9, Feb. 14, 2005.)

## II. ANALYSIS

Summary judgment is only appropriate where the Court is satisfied that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477

U.S. 317, 330 (1986). A genuine issue of material fact exists only if "the evidence is such that a reasonable jury could find for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The burden of establishing the nonexistence of a "genuine issue" is on the party moving for summary judgment. Celotex, 477 U.S. at 330. If the moving party satisfies this burden, the nonmoving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

Defendants argue that they are entitled to summary judgment because "[McMillan's] theory of defect is wholly inconsistent with the undisputed facts of [her] actual medical history." (Defs.' Br. 6.) McMillan responds that summary judgment should be denied because "circumstantial evidence allows an inference to be drawn that Karen McMillan's prosthesis was defective at the time it left [Defendants'] control." (Pl.'s Opp. 9.)

Under McMillan's theory of liability, "[the] prosthetic components were sterilized in such a manner as to cause premature degradation and failure of the prosthetic components." However, as Defendants point out, "[n]one of Plaintiff's medical records reflect that her polyethylene tibial insert wore or degraded more quickly than expected." (Defs.' Br. 6-7.) Moreover, there is no evidence that the method of sterilization—gamma irradiation in

vacuum foil packaging—used on McMillan's prosthesis is associated with any injuries suffered by McMillan. Therefore, the record contains no evidence to support McMillan's theory of liability as expressed in her Responses to Interrogatories.

Even assuming that McMillan's Responses to Interrogatories does not limit her claims to the theory of liability expressed therein, McMillan has still not produced enough evidence to survive summary judgment. McMillan's opposition brief identifies no specific defect in her prosthesis. Under New Jersey law, a plaintiff need not identify a specific defect to prove that she was harmed by a defective product; however, in that case, the plaintiff must demonstrate that the incident that harmed her: "(a) was of a kind that ordinarily occurs as a result of a product defect; and (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution." Myrlak v. Port Auth., 157 N.J. 84, 104 (1999) (citing Scanlon v. Gen. Motors Corp., 65 N.J. 582 (1974)). McMillan contends that the evidence in this case permits a finding that her prosthesis was defective under the holdings of Sabloff v. Yamaha Motor Co., 113 N.J. Super. 279 (App. Div.), aff'd, 59 N.J. 365 (1971), Moraca v. Ford Motor Co., 66 N.J. 454 (1975), and Scanlon.

In Sabloff, the Supreme Court of New Jersey held that "whenever the facts permit an inference that the harmful event

ensued from some defect (whether identifiable or not) in the product, the issue of liability is for the jury." 59 N.J. at 366. The facts of that case, in which the plaintiff was injured after the front wheel of his motorcycle stopped rotating, permitted such an inference because "common sense dictates" that the front wheel of a non-defective motorcycle does not stop rotating absent some "non-mechanical failure," and because the plaintiff had provided evidence tending to exclude all such non-mechanical causes. Sabloff, 113 N.J. Super. at 286. Likewise, in Moraca, the Supreme Court of New Jersey held that a jury could properly infer that a product defect had caused a car accident where the plaintiff testified that the "steering mechanism suddenly locked," and where "[t]here was nothing to indicate that the manner of plaintiff's operation of the vehicle, or the condition of the roadway was a factor in the happening of the accident." 66 N.J. at 459. The evidence also permitted a finding of defect in Scanlon, where the plaintiff proved that the car "malfunctioned violently while being properly operated"; however, the Supreme Court of New Jersey found insufficient evidence in that case that the defective condition "existed while in the control of the defendants." Scanlon, 65 N.J. at 599.

Here, the undisputed evidence shows that McMillan used the prosthesis properly, and that McMillan's revision surgeries were required—the first thirteen months after McMillan's initial

surgery—because of component cement loosening and misalignment. McMillan argues that this evidence, along with the expected fifteen-to-twenty-year life span of her prosthesis,<sup>1</sup> permits a finding that her prosthesis was defective under the reasoning of Sabloff, Moraca, and Scanlon. In those cases, “common sense” alone permitted jury findings that, with proper use, motorcycle wheels did not stop rotating, steering columns did not suddenly lock, and station wagons did not violently malfunction. However, while juries are familiar with cars, they are not familiar with the components of an prosthetic knee implant. Thus, while common sense might allow a jury to reason from a locked steering wheel to a defective car, it does not allow a jury to reason from component cement loosening and misalignment to a defective prosthesis. Absent expert testimony or other additional evidence tending to connect the injuries suffered by McMillan to a defective prosthesis, McMillan has not demonstrated that her injuries are “of a kind that ordinarily occurs as a result of a

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<sup>1</sup> McMillan argues that a product’s age and expected life span are relevant to prove that the product was defective. (See Pl.’s Opp. at 7 (“Under the Scanlon analysis, life span is one of the most important considerations in determining whether an inference that the product was defective is permissible.”).) However, the cases she cites use product age and expected life span not as proof of a defect *per se*, but rather—assuming defect—as proof that such defect existed when the product left the defendant’s control. See White v. ABCO Eng’g Corp., 221 F.3d 293, 302 (2d Cir. 2000); Leo v. Kerr-McGee Chem. Corp., 37 F.3d 96, 100-01 (3d Cir. 1994); Moraca, 66 N.J. at 459; Scanlon, 65 N.J. at 593.

product defect." Therefore, McMillan has provided insufficient proof of product defect to satisfy the Scanlon rule as restated in Myrlak. Because all of McMillan's claims rely on the existence of a product defect (see Pl.'s Resps. Interrogs. ¶¶ 21-24), Defendants' motion for summary judgment will be granted.

The accompanying Order shall issue today.

Dated: August 19, 2005 /s/ Robert B. Kugler  
ROBERT B. KUGLER  
United States District Judge